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## REMARKS

This Amendment is submitted in response to the Office Action dated December 16, 2003. Pursuant to the Preliminary Amendment filed February 1, 2002, Claims 1-9 have been canceled without prejudice or disclaimer, and Claims 10-30 have been added. Applicants submit in the present Amendment the amendments made to the Specification and Claims as previously filed, and Applicants respectfully request full consideration of same. In addition, Claim 21 has been amended for a minor grammatical error. This Amendment does not add new subject matter. Applicants also note for the record that the purpose of this Amendment is to place the claims in proper format and to add new claims. Therefore, Applicants do not intend to disclaim or narrow any subject matter in view of this Amendment.

Claims 1-6 have been rejected under 35 U.S.C. 112, second paragraph and 35 U.S.C. 101, and Claims 4-6 have been objected to. Because these claims have been cancelled pursuant to the Preliminary Amendment, Applicants respectfully submits that these rejections and objections are now moot and, thus, the rejections and objections should be withdrawn.

Claim 3 has been rejected under 35 U.S.C. §112, first paragraph. The Patent Office alleges that the microorganism strain recited in the claim is neither obtainable by a repeatable method set forth in the specification nor is it apparent that the microorganism strain is otherwise readily available to the public. In response, Applicants respectfully submit that a deposit of the microorganism strain (CNCM I-2168) was made in the present application as filed, a copy of which is attached herewith for the Patent Office's review and consideration. Applicants further note that the microorganism strain has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent issued with respect to the present application. Further, Applicants believe that the deposit was properly referred to in the body of the specification as originally filed. Therefore, Applicants believe that subsequently filed Claims 12, 20, 25 and 30 are in compliance with 35 U.S.C. §112, first paragraph, and further that this rejection has been rendered moot and should be withdrawn with respect to Claim 3.

Claim 5 has been rejected under 35 U.S.C. 103(a) as being obvious over *McFarland*. Claim 5 has been cancelled; therefore, Applicants submit that the rejection of this claim is moot and should be withdrawn.

Claims 1-4 and 6-9 have been rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as being obvious over the publication by McFarland et al. ("*McFarland*"). As previously discussed, Claims 1-4 and 6-9 have been cancelled without prejudice or disclaimer, and, thus, this rejection has been rendered moot with respect to same and should be withdrawn. Further, Applicants believe that pending Claims 10-30 are patentable over *McFarland* based on at least the following reasons.

Of the pending Claims 10-30, Claims 10, 16, 21 and 26 are the sole independent claims and thus the remaining claims, respectively, depend therefrom and, as such, include each of the features of the respective independent claims as a matter of law.

The claimed invention is directed to a method of treating diarrhea and a method of preventing infection of intestinal cells of a mammal due to a rotavirus. In Claim 10, the method of treating diarrhea includes administering to a mammal at risk of diarrhea an amount of a lactic acid bacterium of genus *Bifidobacterium* effective to prevent infection of intestinal cells of the mammal due to a rotavirus. In Claim 16, the method of preventing infection of intestinal cells of a mammal at risk of infection due to a rotavirus includes administering to the mammal a composition including a therapeutically effective amount of a *Bifidobacterium* strain. The claimed invention is also directed to compositions capable of preventing infection of intestinal cells of a mammal due to a rotavirus. In Claim 21, a food composition includes one or more *Bifidobacterium* strains capable of preventing infection of intestinal cells of a mammal due to a rotavirus. In Claim 26, a pharmaceutical composition includes one or more *Bifidobacterium* strains capable of preventing infection of intestinal cells of a mammal due to a rotavirus.

In contrast, *McFarland* is distinguishable from the claimed invention. For example, *McFarland* fails to teach or suggest treating diarrhea with an amount of a *Bifidobacterium* to prevent infection of intestinal cells due to a rotavirus as required by Claim 10. *McFarland* teaches that various probiotic bacterial strains can be beneficial in the treatment of diarrhea caused by a depletion of the intestinal microflora via antibiotics or by an infestation of the gut

with pathogenic bacteria. *See McFarland* page 74, col. 1, paragraph 3. However, throughout the lengthy discussion in *McFarland* of the use of certain probiotics in the treatment and prevention of diarrhea, *McFarland* fails to teach or suggest a Bifidobacterium effective to treat or prevent diarrhea. In fact, whereas other probiotics such as *Saccharomyces boulardii*, *Lactobacillus casei* strain GG, *Streptococcus faecium*, *Lactobacillus acidophilus* and *Lactobacillus acidophilus* are taught to be effective in the treatment or prevention of diarrhea, Bifidobacteria are not even mentioned. *See McFarland* pages 74 and 75. *McFarland* only discloses *Bifidobacterium longum* and *Bifidobacterium bifidum* in the context of bacterial infections to be used as commercially available yogurts with the proposed therapeutic activity of reducing erythromycin-induced gastrointestinal effects. *See McFarland* page 74, col. 2, paragraph 2. Therefore, *McFarland* fails to teach or suggest treating diarrhea with an amount of a Bifidobacterium to prevent infection of intestinal cells due to a rotavirus as required by the claimed invention.

Further, *McFarland* fails to teach or suggest preventing infection of intestinal cells of a mammal at risk of infection due to a rotavirus with a therapeutically effective amount of a Bifidobacterium strain as required by Claim 16. Likewise, *McFarland* fails to teach or suggest a Bifidobacterium strain capable of preventing infection of intestinal cells of a mammal due to a rotavirus as required by Claims 21 and 26. As discussed above, *McFarland* merely discloses *Bifidobacterium longum* and *Bifidobacterium bifidum* to reduce antibiotic-induced gastrointestinal effects. *See McFarland* page 74, col. 2, paragraph 2. *McFarland* does not disclose *Bifidobacterium longum*, as claimed in Claims 11, 20, 25 and 30, in the context of rotaviral-mediated diarrhea or even viral infection. Nor does *McFarland* mention *Bifidobacterium adolescentis*, as claimed in Claims 11, 20, 25 and 30, in any context, let alone in any connection with viral infections. Applicants respectfully submit that bacteria and viruses are completely different biological forms having entirely different characteristics and populating different ecosystems. Accordingly, different methods and compositions are required to treat or prevent infections of each different pathogen. The skilled person cannot merely substitute the characteristics of one beneficial bacterium useful to treat bacterial infections such as the probiotics disclosed in *McFarland* to be equally effective to treat viruses. Therefore, Applicants

believe that the skilled artisan would not be inclined to modify *McFarland* to arrive at the claimed invention.

Moreover, the claimed Bifidobacteria are distinguished from the conventional strains of Bifidobacteria disclosed in *McFarland* due to their capability of preventing infection of intestinal cells due to a rotavirus as claimed. The capability to prevent infection of intestinal cells due to a rotavirus is a specific trait unique to the Bifidobacteria strains disclosed and claimed by Applicants and is not common to all strains of Bifidobacteria. See Specification, page 6, lines 8-14. *McFarland* teaches that the effectiveness of probiotics depends on their mere ability to colonize the gastrointestinal tract of an individual to form a physical barrier for any pathogen invading the gut. See *McFarland* page 74, col. 1, paragraph 3. In contrast to this passive role in preventing gastrointestinal infection, however, the Bifidobacteria as claimed play an active role in preventing infection of intestinal cells of a mammal due to a rotavirus as supported in the Specification, for example, on page 5 at paragraph 4. In particular, the active role of the claimed Bifidobacteria includes interaction directly with the rotavirus or interaction with receptors on intestinal cells. The direct binding or scavenging of the rotaviral particles by the Bifidobacteria prevents the virus from invading or infecting the cells. The interaction of the Bifidobacteria with the receptors on intestinal cells which are required by the rotaviruses to enter the cells prevents the attachment of the virus to the viral receptors and the subsequent invasion of the viruses into the intestinal cells. Therefore, *McFarland* fails to teach or suggest a Bifidobacterium strain capable of preventing the infection of intestinal cells due to a rotavirus or the method of preventing infection of intestinal cells due to a rotavirus with a therapeutically effective amount of that Bifidobacterium strain.

As discussed above, *McFarland* neither teaches nor suggests the claimed Bifidobacteria or the amount of Bifidobacteria effective to prevent the infection of intestinal cells of a mammal due to a rotavirus. Further, a skilled person in the art would not have been motivated to modify *McFarland* to make the claimed invention. Thus, the claimed invention as defined by Claims 10 to 30 is distinguishable from *McFarland* and therefore patentable over *McFarland*.

Appl. No. 10/049,368  
Amendment in Reply to Office Action  
Dated December 16, 2003

For the foregoing reasons, Applicants respectfully submit that the present application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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Dated: March 16, 2004

# INDICATIONS RELATING TO DEPOSITED MICROORGANISM OR OTHER BIOLOGICAL MATERIAL

(PCT Rule 13bis)

<p>A. The indications made below relate to the deposited microorganism or other biological material referred to in the description on page <u>3</u>, line <u>16</u></p>	
<p>B. IDENTIFICATION OF DEPOSIT <span style="float: right;">Further deposits are identified on an additional sheet <input type="checkbox"/></span></p>	
<p>Name of depositary institution Collection Nationale de Cultures de Microorganismes Institut Pasteur</p>	
<p>Address of depositary institution (including postal code and country) 25, Rue du Docteur Roux F-75724 Paris Cedex 15</p>	
<p>Date of deposit 15/03/1999</p>	<p>Accession Number NCC 251 - I-2168</p>
<p>C. ADDITIONAL INDICATIONS (leave blank if not applicable) <span style="float: right;">This information is continued on an additional sheet <input type="checkbox"/></span></p>	
<p>D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)</p>	
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# CNCM

Paris, le 16 mars 1999

Collection Nationale  
de Cultures de Microorganismes

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22. März 1999

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Obj : L'enregistrement de quatre bactéries en vue de dépôts aux termes du Traité de Budapest

Cop : Madame Aline MAMIN, Monsieur Roberto RENIERO  
Nestlé Research Centre (CRN), Vers-chez-les-Blanc, C.P. 44, CH-1000 LAUSANNE 26

Monsieur,

Par la présente nous vous confirmons avoir reçu ce jour, en vue de quatre dépôts initiaux suivant la règle 6.1 du Traité de Budapest, douze lyophilisats relatifs à chacun des microorganismes identifiés ci-dessous.

Vos projets de dépôt ont été enregistrés à la CNCM  
à la date du **15 mars 1999** sous les numéros suivants

Référence d'identification

Numéro d'enregistrement CNCM

NCC 251

I-2168

NCC 481

I-2169

NCC 490

I-2170

NCC 585

I-2171

Si un dépôt est accepté, le numéro d'ordre attribué par la CNCM est identique au numéro d'enregistrement et la date du dépôt est la date de l'enregistrement.

Restant à votre disposition,  
nous vous prions d'agréer, Monsieur, l'expression de notre considération distinguée.

*Y. Cerisier*

Mme Y. CERISIER  
Directeur Administratif de la CNCM